IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	) Appeal No.
Andre Colas, Gary Lord, Marie Valencia, and Xavier Thomas	) Group Art Unit 1771
	) Examiner Daniel R. Zirker
Serial No. 09/304,393	)
Filed May 4, 1999	)
Confirmation No. 9604	)
Title Method for Adhering Substrates Using Adhesive Devices Containing Silicone Gels	)
Docket No. VN 24	) July 26, 2004

APPELLANTS' BRIEF UNDER 37 CFR 1.192(a)

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is an appeal from the Final Rejection dated July 2, 2004, in which Claims 1-3, 5, 6, 8 and 10 were finally rejected. Appellants' claims have been twice rejected, and so this appeal is proper under 35 USC 134.

REAL PARTY IN INTEREST

The real party in interest in this application is the assignee of record of the entire interest. The assignee of record of the entire interest is Dow Corning Corporation, Midland, Michigan. The assignment was recorded on July 26, 1999, Reel 010120 Frame 0127.

RELATED APPEALS AND INTERFERENCES

Appellants, appellants' legal representative, or the assignee of record, do not know of any related appeal or interference in any other application, which would directly affect, or be directly affected by, or have any bearing on, the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-10 were originally filed in the application. Only Claims 1-3, 5, 6, 8, and 10 remain in the application. However, pending Claims 1-3, 5, 6, 8, and 10 differ from the original claims in that they have been amended during prosecution to include certain limitations noted by the Board of Appeals in its Decision in Appeal No. 2002-2211 (Paper No. 15 dated March 27, 2003), as being absent from the claims, i.e., "The claimed invention is not limited to specific substrate types". These claims were finally rejected and are the subject matter of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection under 37 CFR 1.116.

SUMMARY OF THE INVENTION

The invention is relatively simple, and relates to a method for adhering a prosthesis to a human or animal body with an adhesive device, and to the prosthesis in combination with the adhesive device for adhering it to a human or animal body. The improvement is directed to the adhesive device that consists of a carrier sheet having two surfaces. One surface of the carrier sheet contains a continuous layer of a silicone gel having a sufficient tack so to adhere to the

prosthesis. The other surface of the carrier sheet contains a continuous layer of a silicone gel having a sufficient tack so as to adhere to the human or animal body. The adhesive device is designed so that it can be easily applied to the human or animal body, and then easily removed from the human or animal body when it needs to be changed, or has served its useful purpose. It is not designed or intended for any permanent attachment of a prosthesis to a human or animal body.

ISSUES

There is one issue for consideration by The Board of Patent Appeals and Interferences. The issue is whether Claims 1-3, 5, 6, 8, and 10 are patentable over Fabo (WO 96/09076) in view of Luckman (Canada 2,101,509) under Section 103(a).

GROUPING OF CLAIMS

The pending claims stand or fall together as a group.

ARGUMENT

As noted above, Claims 1-3, 5, 6, 8, and 10 stand finally rejected as being unpatentable over Fabo (WO 96/09076) in view of Luckman (Canadian 2,101,509) under Section 103(a).

It's noted that the invention involves a method for adhering a prosthesis to a human or animal body with an adhesive device, and to the prosthesis. A carrier sheet with two surfaces has each surface coated with a continuous layer of silicone gel. The silicone gel on one side of the carrier sheet has enough tack to adhere it to the prosthesis, while the silicone gel on the other side of the carrier sheet has enough tack so that it will adhere to the human or animal body. The

adhesive device is designed so that it can be easily applied to the human or animal body, and then easily removed from the human or animal body, whenever it needs to be changed, or it has served its utilitarian purpose. It's not designed or intended to be used for any permanent attachment of a prosthesis to a human or animal body.

In contrast, the primary reference Fabo relates to a scar dressing with a top sheet 4 for preventing a silicone gel layer 2 from adhering to clothing, and a removable protective layer 5 covering a silicone gel layer 3 that is then applied to a human body. As pointed out by the Board of Appeals in it's Decision (Paper No. 15), the claims before the Board at that time, were not limited to specific substrate types. As such, the Board sustained the rejection of the original claims over Fabo. The rationale behind the Board's decision was that the top sheet 4 and the protective layer 5 in Fabo were substrates adhered together with the silicone gel. However, the pending claims have since been limited to include the prosthesis and a human or animal body as the substrates. Fabo fails to disclose anything relating to adhering a prosthesis to a human or animal body using a silicone gel adhesive.

While Luckman teaches a breast enhancement device 10 that is adhered to the chest wall of the wearer with an adhesive 14, the adhesive 14 in Luckman is specifically described as Dow Corning Corporation's *SILASTIC® Medical Adhesive Silicone Type A*. The Examiner's position is that the breast prosthesis in Luckman is adhered to a human body, in the same manner as the present invention. However, there is no carrier sheet in Luckman having two surfaces that contain a silicone gel. Instead, the device in Luckman is intended to be directly and permanently adhered to the user's chest wall with the *SILASTIC® Medical Adhesive Silicone Type A* adhesive layer 14.

The Board will find of record a Data Sheet and a Material Safety Data Sheet (MSDS) describing *SILASTIC® Medical Adhesive Silicone Type A*. As is apparent from a reading of the Data Sheet and the MSDS, the adhesive in Luckman is not a gel. Rather, the Luckman adhesive it is a structural adhesive or sealant, much akin to a cement and/or a glue. The composition is sticky and honey-like before being cured, and then upon cure it forms a strong rubber with a tack free surface after it is cured. The cure is initiated and completed when the adhesive is brought into contact with the substrate. It's chemically bonded to the adhered surface, and is intended to provide permanent attachments that cannot be removed without damaging the substrate.

For example, the Board's attention is directed to the first page of the Data Sheet, where the *SILASTIC® Medical Adhesive Silicone Type A* is described as a being a translucent paste that is used to permanently bond materials. On Page 2, it's said to form a tack-free outer skin a few minutes after being applied.

In contrast, the adhesive silicone gels of the present invention have qualities and behavior profiles akin to pressure sensitive adhesives. In this regard, the silicone gel adhesive-substrate interface does not resist separation when the adhesive is peeled off. Because the silicone gel has excellent wetting, spreadability, and visco-elasticity properties, it's able to quickly adhere to a surface and to develop physical interactions with the surface. It does not develop chemical interactions with the surface as in structural adhesives. Thus, the silicone gel can be easily removed without deteriorating the surface and/or leaving behind a residue.

Because of these differences, the silicone gel of the invention can be characterized as being *comfortable adhesives*, providing soft, movable gel masses against the skin, rather than permanent rubber cements. Moreover, because of their properties, silicone gels retain their tack after being removed, so that silicone gels can be easily removed, moved, and reused. In addition, their unique properties allow for a quick, easy, and comfortable repositioning of any medical prosthesis.

Therefore, appellants cannot see wherein it would be obvious for one skilled in the art to combine Luckman with Fabo, because the device described by Luckman would permanently bond the device to the breast of the wearer, rather than provide an attachment that can be easily removed without causing damage to the underlying surface, which is the objective sought to be obtained in for the scar dressing in Fabo. As such, Luckman's purpose is inconsistent with the purpose in Fabo.

Another reason it would not be obvious for one skilled in the art to combine Luckman with Fabo, is that the Data Sheet on the first page states that during use of *SILASTIC® Medical Adhesive Silicone Type A*, the composition releases acetic acid. It should be apparent that this would not motivate one skilled in the art to look to Luckman for any solution to the problem at hand, i.e., to substitute a prosthesis for the top sheet 4 of the scar dressing in Fabo. It does not appear that one skilled in the art would consider the presence of acetic acid as being desirable in the treatment of scars.

CONCLUSION

The Honorable Board of Appeals is requested therefore to reverse the Examiner's rejection of Claims 1-3, 5, 6, 8, and 10.

HEARING

An oral hearing is not requested.

Respectfully submitted,

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APPENDIX

1. In a method for adhering a prosthesis to a human or animal body with an adhesive device, the improvement comprising the use of an adhesive device comprising:

a carrier sheet, said carrier sheet having at least two surfaces;

on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and

on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body; and wherein the first and second continuous layers of silicone gel are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups in the presence of a platinum or rhodium catalyst.

2. The method according to Claim 1 in which the carrier sheet is non-woven and continuous and is made from a material selected from the group consisting of polysaccharide based materials, polyethylene, polyamide, polyurethane, nylon, polyester, polypropylene, polytetrafluoroethylene, and silicone.

3. The method according to Claim 1 in which the carrier sheet has a density of about 5 to 150 g/m^2 and a thickness in the range of about 0.01 to about 1 mm.

5. The method according to Claim 1 in which the first and second continuous layers of silicone gel have a thickness in the range of about 0.2 to 5 mm.

6. The method according to Claim 1 in which the first and second continuous layers of silicone gel are covered by release liners.

8. A prosthesis having an adhesive device for adhering it to a human or animal body comprising:

a prosthesis having a surface to be adhered to a human or animal body; and

on the surface of the prosthesis to be adhered to the human or animal body, an adhesive device comprising:

a carrier sheet, said carrier sheet having at least two surfaces;

on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and

on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body,

wherein the first continuous layer of silicone gel of the adhesive device is adhered to the surface of the prosthesis to be adhered to a human or animal body; and wherein the first and second continuous layers of silicone gel are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups in the presence of a platinum or rhodium catalyst.

10. A method for adhering a prosthesis to a human or an animal body comprising:

positioning an adhesive device between the prosthesis and the human or animal body; and

compressing the adhesive device between the prosthesis and the human or animal body, wherein the adhesive device comprises:

a carrier sheet, said carrier sheet having at least two surfaces;

on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and

on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body; and wherein the first and second continuous layers of silicone gel are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups in the presence of a platinum or rhodium catalyst.